K063510

SECTION E – 510(k) SUMMARY

JAN 26 2007

Submitter's Name and Address:

Medtronic Emergency Response Systems
11811 Willows Road Northeast
Redmond, WA 98052

Contact Person:

Michelle Ackermann
Senior Regulatory Affairs Specialist

Date Summary Prepared:

January 3, 2007

Device:

Medtronic LIFEPAK® 12 Defibrillator/Monitor

Classification:

Classification Name	Class
Low Energy DC-Defibrillator	II
Automatic External Defibrillator	III
Cardiac Monitor (Including Cardiotachometer & Rate alarm)	II
Cardiac External Transcutaneous (Non-invasive) Pacemaker	II
Oximeter	II
Noninvasive Blood Pressure Measurement System	II
Blood Pressure Computer	II
Carbon Dioxide Gas Analyzer	III

Substantial Equivalence:

The features and functions of the modified LIFEPAK 12 defibrillator/monitor are substantially equivalent to the previously cleared LIFEPAK 12 defibrillator/monitor (K041459, K040775, K033275, K010918, K002445, K990338, K991910, K973486).

Description:

The LIFEPAK 12 defibrillator/monitor was designed for use in a variety of hospital and pre-hospital settings including emergency departments, critical care areas, and air and ground ambulances. The LIFEPAK 12 defibrillator/monitor is powered by either a battery or AC power. LIFEPAK 12 defibrillator/monitor features include manual and automated external defibrillation, noninvasive pacing, ECG monitoring (3-lead, 7-lead and interpretive 12-Lead), pulse oximetry, synchronized cardioversion, noninvasive blood pressure monitoring, end-tidal CO2 monitoring, and invasive pressure monitoring.

The LIFEPAK 12 defibrillator/monitor has been modified with new setup options in automated external defibrillation (AED) mode to give medical directors or physicians flexibility in establishing their AED protocols including consistency with the recently updated 2005 AHA Guidelines for CPR and ECC.

Intended Use:

In automated external defibrillation mode, the LIFEPAK 12 defibrillator/monitor is intended for use on patients in cardiopulmonary arrest by personnel who are authorized by a physician/medical director and have, at a minimum, the following skills and training:

- CPR training
- AED training equivalent to that recommended by the American Heart Association
- Training in the use of the LIFEPAK 12 defibrillator/monitor in automated external defibrillation mode

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Indications for Use:

Manual Defibrillation:

Indications
Defibrillation is indicated for the termination of certain potentially fatal arrhythmias, such as ventricular fibrillation and symptomatic ventricular tachycardia. Energy delivered in the synchronized mode is a method for treating atrial fibrillation, atrial flutter, paroxysmal supraventricular tachycardia, and, in relatively stable patients, ventricular tachycardia.

Contraindications
Defibrillation is contraindicated in the treatment of Pulseless Electrical Activity (PEA), such as indioventricular or ventricular escape rhythms, and in the treatment of asystole.

Automated External Defibrillation:

Indications
AED mode is to be used only on patients in cardiopulmonary arrest. The patient must be unconscious, pulseless, and not breathing normally before using the defibrillator to analyze the patient's ECG rhythm. In AED mode, the LIFEPAK 12 defibrillator/monitor is not intended for use on pediatric patients less than 8 years old.

Noninvasive Pacing:

Indications
Noninvasive pacing is indicated for symptomatic bradycardia in patients with a pulse.

Contraindications: Noninvasive pacing is contraindicated for the treatment of ventricular fibrillation and asystole.

12-lead Electrocardiography:

Indications
The 12-lead electrocardiogram is used to identify, diagnose and treat patients with cardiac disorders and is useful in the early detection and prompt treatment of patients with acute myocardial infarction.

Pulse Oximetry:

Indications
Pulse Oximetry is indicated for use in any patient who is at risk of developing hypoxemia.

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Noninvasive Blood Pressure Monitoring:

Indications

Noninvasive blood pressure monitoring is indicated for detection in trends of hypertension or hypotension. These include patient conditions indicated by abnormalities in various physiologic parameters such as shock, evaluation of perfusion during dysrhythmias, major fluid shifts, evaluation of response to fluid therapy, and titration of vasoactive and cardiotonic drugs. Noninvasive blood pressure monitoring may be useful during ECG monitoring or for post-defibrillation recovery analysis.

End-Tidal CO2 monitoring:

Indications

$EtCO_2$ monitoring is indicated for detection of trends in the level of expired CO_2. It is used for monitoring breathing efficacy and treatment effectiveness in acute cardiopulmonary care, for example, to determine if adequate compressions are being performed during CPR or to rapidly detect whether an endotracheal tube has been placed successfully. It is intended for use on adult and pediatric patients.

Invasive Pressure Monitoring:

Indications

The LIFEPAK 12 invasive pressure monitor is indicated for use in measuring arterial, venous, intracranial and other physiological pressures using and invasive catheter system with a compatible transducer. It may be used on the adult or pediatric patient.

Technological characteristics of new and predicate device:

The new cprMAX setup options only affect operation in automated external defibrillation mode. Other features and functions of the modified LIFEPAK 12 defibrillator/monitor are the same as those of the predicate device.

Summary of Design Controls:

This 510(k) includes a summary of design control activities and a declaration of conformity to design controls.

The information in this 510(k) notification demonstrates that the modified LIFEPAK 12 defibrillator/monitor is substantially equivalent to the predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 26 2007

Medtronic Emergency Response Systems
C/O Michelle Ackermann
Senior Regulatory Affairs Specialist
11811 Willows Road Northeast
Redmond, WA 98052

Re: K063510
Trade/Device Name: Lifepak 12 Defibrillator/Monitor
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III
Product Code: MKJ, LDD, DRT, DRO, DQA, DXN, DSK, CCK
Dated: December 27, 2006
Received: December 28, 2006

Dear Ms. Ackermann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION D – STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): not yet assigned

Device Name: **LIFEPAK 12 Defibrillator/Monitor**

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Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

B Gramm Page 1 of 3
(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K063510

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